

REMARKSClaim Rejections – 35 U.S.C. §112

Claim 3 was rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite because it refers to Figure (1). Applicants respectfully traverse this rejection.

According to MPEP § 2173.05(s):

Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant’s convenience.” *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Consistent with MPEP § 2173.05(s), incorporation by reference of Figure (1) into claim 3 is necessary because it is not practical to duplicate the X-ray diffraction pattern in the claim, and it is not possible to describe it accurately in words. Applicants also note that incorporation by reference of X-ray diffraction patterns into patent claims is a standard practice in the pharmaceutical compound art. See, e.g., recently granted U.S. Patent Nos. 7,148,231, 7,074,928, 7,060,712, 7,015,238, 6,998,503, 6,958,337 and 6,900,221. In fact, the Primary Examiner on U.S. Patent No. 7,148,231 was James O. Wilson, who is named as the Examiner’s supervisor on the Office Action. Accordingly, Applicants respectfully request reconsideration of this rejection.

Claims 2 and 10 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because they recite the relative term “substantially.” According to the Examiner, the term “substantially” is not defined by the claim, the specification does not provide an appropriate standard, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully traverse this rejection.

According to MPEP 2173.05(b):

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Applicants submit that, contrary to the Examiner's position, one skilled in the art would ascertain the scope of the claimed subject matter in light of the specification. The paragraph bridging pages 7 and 8 of the instant specification clearly delineates the scope of "substantially free of crystalline forms" recited in claims 2 and 10. Accordingly, Applicants respectfully request reconsideration of this rejection.

Claim Rejections – 35 U.S.C. §§ 102 and 103

According to the instant Office Action, the rejection of claims 1-18 has been maintained for the reasons of record set forth in the prior Office Action dated May 17, 2006.

In the prior Office Action, claims 1-3 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tang et al. (J. China Pharm. Univ., 2002; hereinafter "Tang") and Pflum et al. (Organic Process Research & Development, 2001; hereinafter "Pflum"). According to the Examiner, Tang and Pflum teach the claimed amorphous levocetirizine dihydrochloride.

In response, Applicants noted in their prior Amendment and Response dated August 16, 2006, that although the English portions of Tang apparently disclose the isolation of levocetirizine dihydrochloride, there is no teaching or suggestion that the levocetirizine dihydrochloride was amorphous. Similarly, Applicants noted that although Pflum discloses the synthesis of levocetirizine dihydrochloride, there is no teaching or suggestion that the prepared levocetirizine dihydrochloride was amorphous.

In the prior Office Action, claims 4-16 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Van de Venne et al. (U.S. Patent 6,489,329; hereinafter "Van de Venne"). According to the Examiner, Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, the same compositions recited in claims 4-16.

In response, Applicants noted in their prior Amendment and Response that although Van de Venne discloses compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, there is no teaching or suggestion that the levocetirizine dihydrochloride was amorphous,

In the prior Office Action, claims 17 and 18 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Van de Venne. According to the Examiner, Van de Venne teaches compositions comprising levocetirizine dihydrochloride. The Examiner acknowledged that the reference fails to disclose the claimed moisture content. However, according to the Examiner, it would have been obvious to one skilled in the art at the time of the invention to obtain the claimed composition because obviousness based on similarity of structure and function entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties.

In response, Applicants again noted in their prior Amendment and Response that Van de Venne fails to teach or suggest amorphous levocetirizine dihydrochloride, let alone the desirability of the claimed moisture content.

In support of the maintenance of the §§ 102 and 103 rejections in the instant Office Action, the Examiner quotes the following portions from MPEP § 2112, entitled "Requirements of Rejection Based on Inherency":

I. SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

...

The claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254 195 USPQ 430, 433 (CCPA 1977).

...

III. A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.

According to the Examiner, the cited references explicitly teach the compound, the "unknown property" in this case being the particular crystalline form. The Examiner then cites to *Ex parte Anderson*, 21 USPQ2d 1241, 1251 (Bd. Pat. App. & Inter. 1991) for the proposition that "there is ample precedent for shifting the burden to an applicant

to reproduce a prior art product whose final structure or properties are, at least, in part determined by the precise process used in its manufacture.”

Applicants respectfully traverse this rejection.

MPEP § 2112 makes it clear that in applying an inherency rejection, the evidence must show that the so-called “unknown property” is necessarily present in the described material:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

MPEP § 2112 also states that the evidence pointed to by the Examiner must have a basis in fact and/or technical reasoning: “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant’s invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner had applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was “formed from a thin flexible inelastic, high tensile strength,

biaxially oriented synthetic plastic material.” *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl’s balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Here, the generalized passages pointed to in Tang, Pflum and Van de Venne by the Examiner do not provide a basis in fact and/or technical reasoning that the allegedly inherent characteristic, in this case amorphous levocetirizine dihydrochloride, necessarily flows from the teachings of the applied prior art. As discussed above, Tang, Pflum and Van de Venne at most disclose levocetirizine dihydrochloride, with no teaching or suggestion that it was in the amorphous state. As such, Applicants submit that it is error for the Examiner to shift the burden to the applicants to reproduce the prior art levocetirizine dihydrochloride and demonstrate that it is not amorphous.

In re Best and Ex parte Anderson, relied upon by the Examiner, are not to the contrary. In *Best*, product claims directed to crystalline zeolitic aluminosilicate were rejected as unpatentable over Hansford. The claims recited six specific parameters, while Hansford disclosed only two. The court upheld the rejection, however, because Hansford expressly disclosed the same process as that used to make the claimed aluminosilicate, except for a functionally expressed rate of cooling. The court found that any sample of Hansford’s would necessarily be cooled to facilitate subsequent handling. See 562 F.2d at 1254-56.

In *Anderson*, claims directed to interpolymers of ethylene and alpha-olefins were rejected as anticipated by the work of Witt and Leatherman. The applicant admitted that Witt and Leatherman made copolymers of ethylene and pentene and hexane at a date earlier than that of the claimed invention, and that these copolymers had melt index, density, comonomer weight percent and present crystallinity values within the ranges recited in the claims. The claims, however, recited tear strength values which Witt and Leatherman did not measure. The applicant argued that it was improper for the examiner to place the burden on the applicant to establish that Witt and Leatherman copolymers did not inherently possess the recited tear strength values. The board disagreed, finding that the PTO can require an applicant to prove that a prior art product lacks an inherent characteristic where there is identity or substantial identity between

the products and the processes used in their manufacture. See 21 USPQ2d at 1251-53.

Here, in contrast to *Best* and *Anderson*, the Examiner has not shown that: 1) the levocetirizine dihydrochloride in Tang, Pflum or Van de Venne was produced by a process similar in nature to that disclosed at pages 11-12 of the instant application; or 2) that the claimed levocetirizine dihydrochloride and the levocetirizine dihydrochloride in Tang, Pflum or Van de Venne exhibit an identity or substantial identity of express characteristics at a sufficient level, to justify the conclusion that the any of the prior art levocetirizine dihydrochlorides is amorphous.

It is well-known in the art that different polymorphic forms of a pharmaceutical compound that exhibits polymorphism generally result from variations in the processing conditions. This is explained in the article by A. Goho, "Tricky Business," *Science News*, Vol. 166, pages 122-123, August 21, 2004, an eight-page website reprint being provided herewith for convenience. Another relevant article is A. M. Rouhi, "The Right Stuff," *Chemical and Engineering News*, Vol. 81, No. 8, pages 32-35, February 23, 2003, and a copy is provided herewith for convenience. Accordingly, Applicants submit that claims 1-18 cannot reasonably be considered as anticipated under §102(b) or rendered obvious under §103(a), and reconsideration of the rejection is respectfully requested.

CONCLUSION

It is believed that examined claims 1-18 are now in condition for allowance, early notice of which would be appreciated. If any minor matters remain to be resolved for disposition of the application, please contact the undersigned to arrange for a telephonic or personal interview.

Respectfully submitted,

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